

EXHIBIT 1

Merits Report and Expert Declaration
of Joel Winterton in the Montana AWP Litigation
February 8, 2007

I. INTRODUCTION

A. QUALIFICATIONS AND EXPERIENCE

1. My name is Joel Winterton. I own the independent management consulting firm of S•E•T Enterprises located in Fountain Hills, Arizona. I have 20 years of experience in the distribution channel dynamics of the pharmaceutical industry, in addition to 10 years of financial information systems design and development experience. My particular specialties over the past 16 years have been the Medicaid program and commercial contracting of pharmaceutical products. ¶
2. I received my Associate of Science degree in Computer Science from the College of the Sequoias in 1977. From 1977 to 1986, I developed various financial systems for the agricultural industry. In 1986, I received a Bachelor of Science degree in Finance from Fresno State University.
3. From 1986 through 1990, I was the software development manager for a nationwide drug wholesaler. While working for this drug wholesaler, I developed expertise in the field of channel dynamics within the pharmaceutical industry. Channel dynamics includes the analysis of product distribution and pricing models to customer groups representing the pharmaceutical delivery channel. These customer groups include retail pharmacies, chain drug stores, health maintenance organizations, hospitals, clinics, long term care facilities, government agencies, pharmaceutical manufacturers and various other entities either supplying pharmaceutical products to or purchasing pharmaceutical products from the wholesale distribution channel. During my tenure, I led the development of several on-line, real time product acquisition systems for

retail pharmacies, hospitals, health maintenance organizations and various other dispensing and delivery customers. These systems were industry leading applications based on the complete understanding of product selection and acquisition dynamics throughout the pharmaceutical distribution channel.

4. From 1988 through 1990, I served as a member of the industry-wide Technical Standards Committee of the National Wholesale Druggists' Association (NWDA). This committee reviewed business trading practices between pharmaceutical industry participants and developed standards for business to business communications between trading partners. For my service on the Technical Standards Committee, I received an NWDA Award for Outstanding Service for contributions made in the development of industry standards for communicating contracting, pricing and inventory information between pharmaceutical industry trading partners.
5. Between 1990 and 1995, I led pharmaceutical industry practices within the consulting firms of Computer Sciences Corporation (CSC) and American Management Systems (AMS), specializing in the areas of government pricing, Medicaid rebates and commercial contracting. While at CSC, I also worked with CSC's Government Services Division that developed and maintained claim processing systems for state Medicaid agencies to gain a better understanding of the Medicaid environment from the State reimbursement and pharmacy dispensing perspectives. CSC and AMS deliver management consulting and information system development services to a broad spectrum of health care entities, including retail pharmacies, government agencies, hospitals and pharmaceutical manufacturers.

6. In 1995, I started S•E•T Enterprises, an independent management consulting firm. S•E•T Enterprises provides consulting services to the pharmaceutical industry in matters concerning Medicaid, government pricing, Medicare and commercial contracting. During my consulting career, I have been engaged by nine of the ten largest pharmaceutical manufacturers on Medicaid-related issues and am considered an industry expert in understanding the pricing dynamics associated with the Medicaid drug rebate program.
7. While at S•E•T Enterprises, I have also served as an industry expert on multiple cases involving the creation of State Medicaid drug formularies (preferred drug lists) to control product utilization by Medicaid drug recipients.

B. OVERVIEW OF REPORT

8. I have been asked by counsel for AstraZeneca to address the liability and damages analysis presented by Professor Raymond S. Hartman in his Declaration of June 13, 2006 ("Original Declaration") and his Supplemental Declaration of June 20, 2006.
9. This report is focused on claims related to the Montana Medicaid program. AstraZeneca manufactures a number of outpatient drugs that are reimbursed under the Medicaid program. In this report, I focus on five AstraZeneca products reimbursed by Montana Medicaid: Prilosec (omeprazole), Seroquel (quetiapine), Nexium (esomeprazole), Pulmicort Respules (budesonide inhalation suspension) and Accolate (zafirlukast).¹ These products comprise 82.4% of the Medicaid spending for the State on AstraZeneca drugs between 1991 and 2004. In contrast, the

¹ These products were chosen because they are the five largest AstraZeneca Montana Medicaid products not subject to a Federal Upper Limit through 2004.

physician-administered drug Zoladex (goserelin acetate implant) represents less than 1% of Montana's Medicaid spending on AstraZeneca products.

10. I explain in my report the pricing and economics underlying these covered outpatient drugs, including the effect of rebates paid by AstraZeneca to the State with respect to these products. In doing so, I will refer to two terms used by Plaintiff's expert – Average Wholesale Price ("AWP") and Wholesale Acquisition Cost ("WAC"). WAC is the undiscounted list price AstraZeneca charges for its products. AWP is a well-known reimbursement benchmark that bears a constant mathematical relationship to WAC for any given AstraZeneca drug. The relationship is typically that the AWP for an AstraZeneca drug is 20% or 25% greater than the WAC for that drug. Both WAC and AWP are publicly available prices for AstraZeneca's drugs that are used by industry participants and State Medicaid agencies.
11. As explained below, in the context of the Medicaid program, prescriptions for branded pharmaceutical products are written by physicians and are typically dispensed by retail pharmacies as written (so long as the product is covered by Medicaid within the State). The physician does not purchase the product and therefore has no economic incentive to prescribe one product over another. The pharmacist dispenses the prescription as written and has no ability to choose one product over another with respect to branded self-administered drugs.
12. There is a unique feature under the Medicaid Rebate Law which Plaintiff's expert ignores. The Medicaid Rebate Law contains provisions which offset the effect on state Medicaid agencies of price increases or discounting by pharmaceutical

manufacturers by increasing the Medicaid rebate amount paid by manufacturers (thereby reducing the agencies' actual net cost). The Medicaid Rebate Law requires manufacturers to calculate Average Manufacturer Prices ("AMPs") and Best Prices ("BPs") and pay Medicaid rebates based on the prices paid by commercial customers. These provisions reduce the net cost of AstraZeneca's covered outpatient drugs to state Medicaid agencies. For example, AstraZeneca's rebates on their two largest branded covered outpatient drugs have increased 72.4% and 206.3%, respectively, since the products entered the market.² These rebate increases have reduced the Montana Medicaid agency's cost for these products accordingly. The State's net cost for Seroquel 200mg, for instance, the largest AstraZeneca Medicaid product in 2004, decreased from \$1.007878 per unit at launch to \$0.993910 per unit during 4Q 2004.

13. Plaintiffs suggest that the spread between pharmacy acquisition cost and AWP was excessively large. With respect to AstraZeneca drugs, that was not the case. Using the Plaintiff's expert's assumption of pharmacy acquisition cost being equal to WAC,³ the difference between the pharmacy acquisition cost and AWP for AstraZeneca's covered outpatient drugs was either 16.67% or 20% during the time period. In many cases, the actual difference was much less based on wholesaler markups to retail pharmacies.

14. In addition, the cost to the Medicaid program was significantly less than actual pharmacy acquisition cost when the effect of Medicaid rebates is included. For five of AstraZeneca's top products, the Medicaid program cost was between 8.5% and

² Analysis of Prilosec 20mg and Seroquel 200mg Medicaid rebate rate changes from first product reimbursement by the State through 4Q 2004.

³ Declaration of Dr. Raymond S. Hartman: Calculation of Damages to Montana, June 13, 2006 ¶ 22.

19.0% less than pharmacy acquisition cost when the effect of Medicaid rebates is taken into account.

15. In the real world, state Medicaid agencies are not responsible for the entire cost of pharmaceutical products dispensed to Medicaid recipients. The State's actual net cost is the drug reimbursement cost less the Medicaid rebate less the federal matching funds rate. In the case of AstraZeneca's two largest Medicaid products, the actual net costs are significantly less than the State reimbursed amount⁴ (80.0% less for Prilosec 20mg and 80.9% less for Seroquel 200mg). In fact, changes in the net costs for these products (accounting for 72.1% of the State's Medicaid reimbursements for AstraZeneca covered outpatient drugs) were significantly below increases in the Consumer Price Index-Urban (CPI-U) from the first reimbursement by the State for each product through 4Q 2004 (0.8% increase for Prilosec 20mg net costs versus a 26.9% increase in the CPI-U and a 1.4% *decrease* for Seroquel 200mg net costs versus a 17.1% increase in the CPI-U).
16. With respect to AstraZeneca's drugs, Plaintiffs also overlook the impact of dispensing costs on pharmacy margins. Pharmacy reimbursement is a function of two factors: the product based reimbursement (e.g., AWP-10% for the State of Montana⁵) and the dispensing fee reimbursement paid to the pharmacy (e.g., \$2.00 for each prescription for the State of Montana).⁶ It is a well-publicized fact that the State of Montana

⁴ 4Q 2004 ratio of Medicaid Net Costs to State Reimbursement Costs for Prilosec 20mg and Seroquel 200mg.

⁵ National Pharmaceutical Council: Pharmaceutical Benefits Under State Medical Assistance Programs, 2000.

⁶ National Pharmaceutical Council: Pharmaceutical Benefits Under State Medical Assistance Programs, 2000.

under-reimburses pharmacies for the cost of dispensing Medicaid prescriptions.⁷

When the impact of both the product and dispensing fee reimbursements are considered, the reality is retail pharmacies operate on razor thin margins when dispensing Medicaid products, and for most AstraZeneca covered outpatient drugs they incur a slight loss on every prescription.

D. DATA SOURCES USED IN ANALYSIS

17. In preparing this analysis, I utilized a variety of AstraZeneca data extracts, industry trade association reports, published materials from government agencies and items published in the Federal Register. Below is a summary listing of the data sources used in my analysis:

- AstraZeneca pricing data (Average Wholesale Price, Wholesale Acquisition Cost, Average Manufacturer Price, Best Price & Medicaid Rebate Per Unit for the years 1991 through 2004);
- AstraZeneca Medicaid Claim History (paid Medicaid units & paid Medicaid rebates);
- National Pharmaceutical Council: Pharmaceutical Benefits Under State Medical Assistance Programs;
- United States Department of Labor: Consumer Price Index - Urban;
- Federal Register: Federal Medical Assistance Percentages;
- Centers for Medicare & Medicaid Services: Medicaid Statistical Information System (MSIS), Medicaid Prescription Reimbursement Information By State, and State Drug Utilization Data;
- United States Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation: Historical and Projected Trends in Medicaid; and
- United States Bureau of the Census, Population Division: State and National population figures.

⁷ Montana Pharmacy Association 2002 Survey of Montana Community Pharmacies.

II. THE ECONOMICS ASSOCIATED WITH ASTRAZENECA'S COVERED OUTPATIENT DRUGS

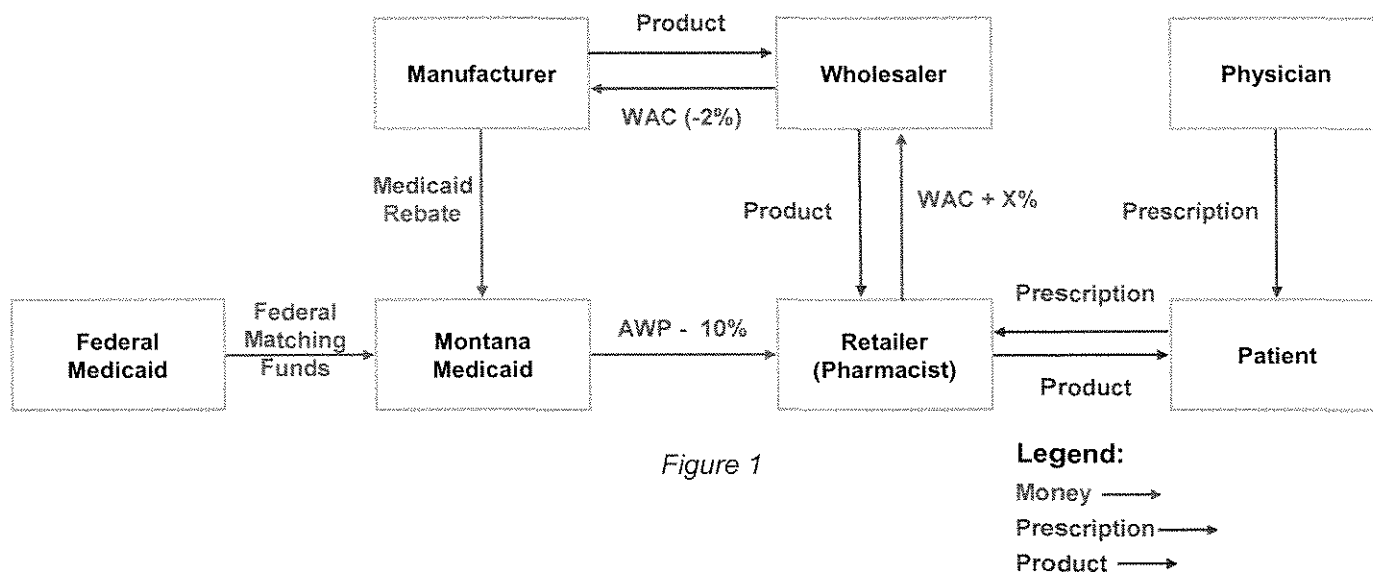
A. ANALYSIS OF THE MEDICAID PRICING ENVIRONMENT

18. As we see in Figure 1 (Medicaid Environment), retail pharmacies acquire products from wholesalers at WAC or in some cases slightly above.⁸ For branded pharmaceutical products, the pharmacist dispenses the prescription as written and is then reimbursed by the Medicaid program according to the reimbursement level set by the State. The State also receives a Medicaid rebate from the manufacturer and matching funds from the federal government based on the published rates. For Fiscal Year ("FY") 2004, the Montana federal matching rate was 72.85%.⁹ Since the prescriber (physician) and dispenser (pharmacy) are two different entities, the product selection decision is not connected to the product acquisition decision. The State's reimbursement to the pharmacy is offset by both the manufacturer rebate payment and the federal matching funds payment, thereby reducing the State's net cost.

⁸ Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products, Department of Health and Human Services, September 16, 2002.

⁹ Federal Register: November 15, 2002 (Volume 67, Number 221), ¶¶ 69223-69225.

Medicaid Environment



19. During the beginning of the Medicaid rebate program (FY 1991), the reimbursement rates for 44 States were based on AWP and ranged between 0% and 12% off AWP.¹⁰ Four states used WAC as the reimbursement basis with ranges from 7% to 10% over WAC. Two states utilized an AWP/WAC combination reimbursement rate using the lower of AWP less a percentage and WAC greater than a percentage. For the WAC-based states, they estimated pharmacy acquisition costs to be above WAC (7% to 10%) for FY 1991. The current (4Q 2006) Medicaid product reimbursement rate for the State of Montana is AWP less 15%,¹¹ five years after receiving Average Sale Prices from pharmaceutical manufacturers.

¹⁰ National Pharmaceutical Council – Pharmaceutical Benefits Under State Medical Assistance Programs.

¹¹ Centers for Medicare and Medicaid Services: Medicaid Prescription Reimbursement Information By State.

20. During the late 1980s and early 1990s, pharmacy acquisition cost included a wholesaler sales markup with typical ranges between 3% to 7% of WAC. These sales markups were negotiated between wholesalers and pharmacies. Any wholesaler markup would further close the gap between the State's reimbursement for AstraZeneca's branded covered outpatient drugs and the actual acquisition cost paid by pharmacies.
21. The Medicaid Rebate Law¹² was enacted in November of 1990 to provide both a funding source for the Medicaid program and to offset the effect on Medicaid of price increases or discounting by pharmaceutical manufacturers. These offsets are accomplished by increasing the Medicaid rebate amount paid to state Medicaid agencies (thereby reducing the agencies' actual net cost). The Medicaid rebate amount is the sum of the basic rebate amount and the penalty rebate amount. The basic rebate amount (for branded covered outpatient drugs) is calculated as the greater of the AMP times a minimum discount percentage (12.5% during 1991 and currently 15.1%) or the AMP less the BP (lowest price to any commercial customer). The supplemental rebate amount is the current AMP minus the baseline AMP (the price established when the product was launched) increased by the change in the Consumer Price Index – Urban ("CPI-U") over the same time period. This rebate provides offsets to the Medicaid program when prices rise faster than the CPI-U. The statute requires manufacturers to calculate and submit on a quarterly basis both the AMP and BP to the federal government. AstraZeneca has done so every quarter since 1991.

¹² 42 U.S.C. § 1396r-8.

22. The AMP is the average price paid to the manufacturer for sales to certain trade classes during the quarter taking into consideration all cash discounts and other price reductions which reduce the price actually paid.¹³ The BP is the lowest price at which the manufacturer sells the product to any purchaser in the United States, excluding some sales to certain federal agencies.¹⁴ The AMP and BP are both submitted to the government on a quarterly basis and a baseline AMP is established for each branded product.¹⁵
23. AstraZeneca has participated in the Medicaid rebate program since its inception, and pays state Medicaid agencies rebates based on utilization data submitted by states on a quarterly basis. The Medicaid Rebate Law has resulted in significant Medicaid rebates paid by AstraZeneca to state Medicaid agencies, and these disbursements have had the effect of reducing the net cost actually paid by these agencies. Figure 2 shows a comparison of Montana pharmacy acquisition cost compared to the Medicaid program's net cost when considering the State reimbursement rate and the effect of Medicaid rebates. For five of AstraZeneca's top products, the average net Medicaid cost is between 8.5% and 19.0% less than the pharmacy acquisition cost (from product launch through 2004).

¹³ Medicaid Rebate Agreement between the Secretary of Health and Human Services and pharmaceutical manufacturers participating in the Medicaid program.

¹⁴ Medicaid Rebate Agreement between the Secretary of Health and Human Services and pharmaceutical manufacturers participating in the Medicaid program.

¹⁵ As a result of the settlement agreement with Montana, signed September 4, 2003, AstraZeneca began providing Montana with average selling prices on eight classes of injectible drugs (Cefotan, Elavil Injection, Faslodex, Foscavir, Merrem, Tenormin Injection, Xylocaine Injection and Zoladex). A letter was sent by AstraZeneca on November 14, 2003 to the Montana Department of Public Health and Human Services containing the average selling prices of the above drugs for 3Q 2003. The State of Montana received this letter and had access to AstraZeneca's average selling prices on these drugs on November 17, 2003. Letter to Montana Department of Public Health and Human Services, November 14, 2003.

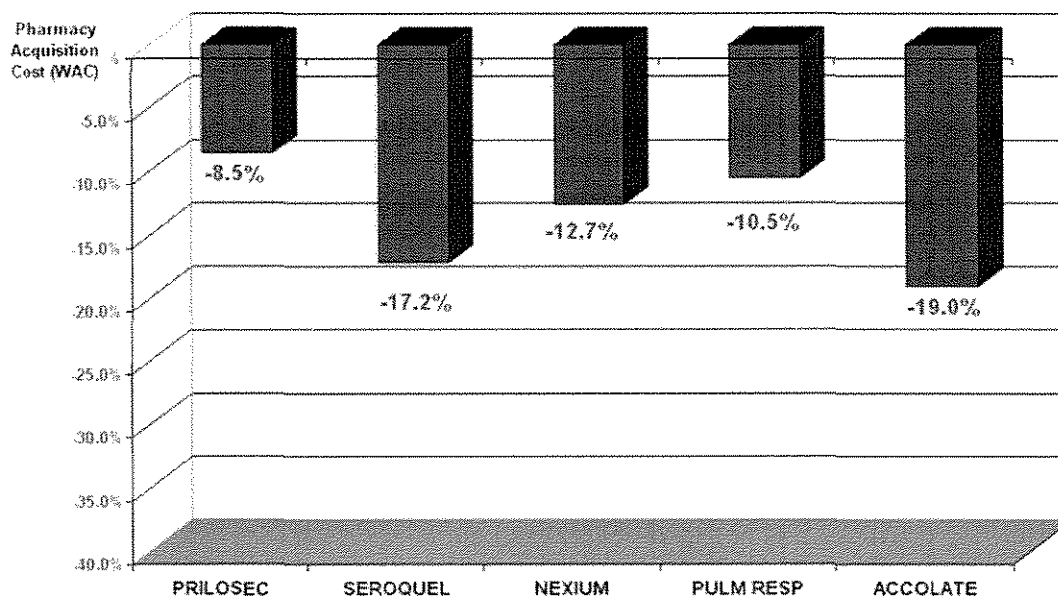


Figure 2

24. For example, in the case of AstraZeneca's two largest Medicaid products (Prilosec and Seroquel – representing 72.1% of the State's reimbursement for AstraZeneca products between 1991 and 2004), Medicaid rebates have ensured that the State's net cost has not grown faster than the CPI-U rate.

25. Since the first reimbursement to pharmacies by the State for Prilosec 20mg through 4Q 2004, AstraZeneca has increased the WAC price 22.0%, the Medicaid rebate rate has increased 72.4%, and the State's net cost after rebates and federal matching funds has increased 0.8%, while the CPI-U increased 26.9%.

26. Since the first reimbursement to pharmacies by the State for Seroquel 200mg through 4Q 2004, AstraZeneca has increased the WAC price 34.9%, the Medicaid rebate rate has increased 206.3%, and the State's net cost after rebates and federal matching funds has actually *decreased* 1.4%, while the CPI-U increased 17.1%.

27. Increases in spending for the State's Medicaid program can be traced to other market dynamics. Figure 3 shows the trends in the total state population as compared to total Medicaid and Medicaid drug recipients. Between 1991 and 2003, the total state population for Montana has increased 14%, while the total Medicaid population has increased 74% and the Medicaid drug recipient population has increased 64%. This increase in the number of Medicaid recipients has had the effect of increasing Montana's Medicaid expenditures.

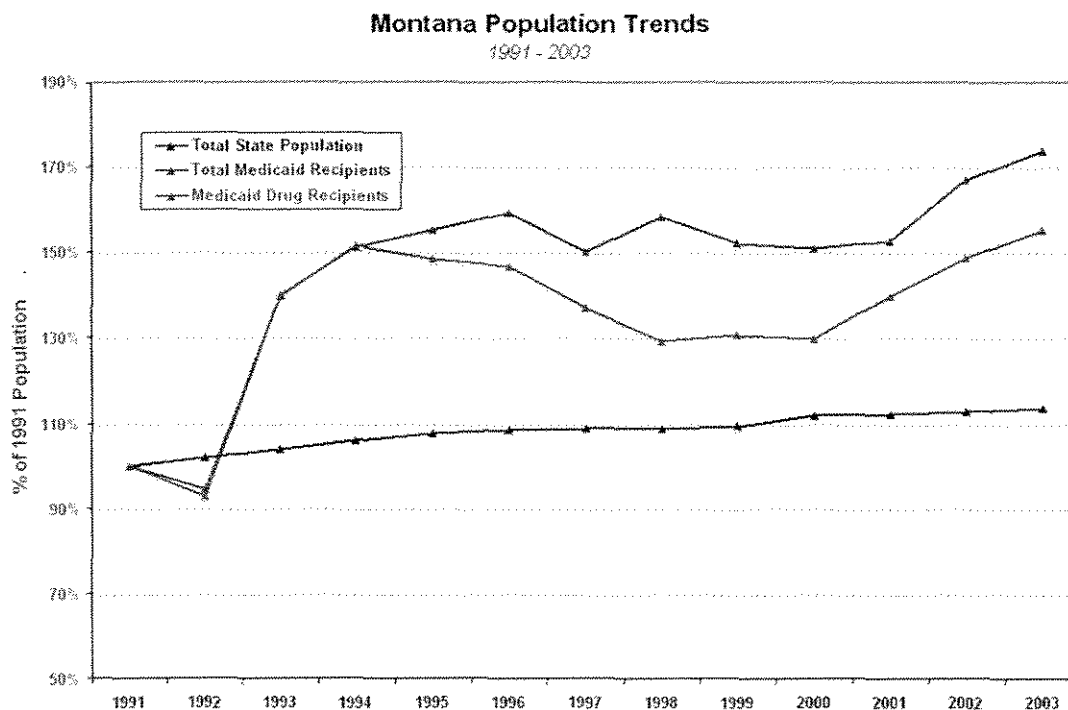


Figure 3

28. In addition to the increase in recipients, Montana has also increased its reliance on pharmaceutical products to lower overall healthcare costs to the Medicaid program. Figure 4 shows the percentage of spending on pharmaceutical products as compared to total Medicaid expenditures for the State. From 1991 to 2003, the percentage of spending on pharmaceuticals has increased from 7.4% to 16.2% of the total Medicaid budget. Based on the pricing dynamics of top AstraZeneca Medicaid products, any similar increase in cost borne by the State is reflective of the increased utilization of AstraZeneca products.

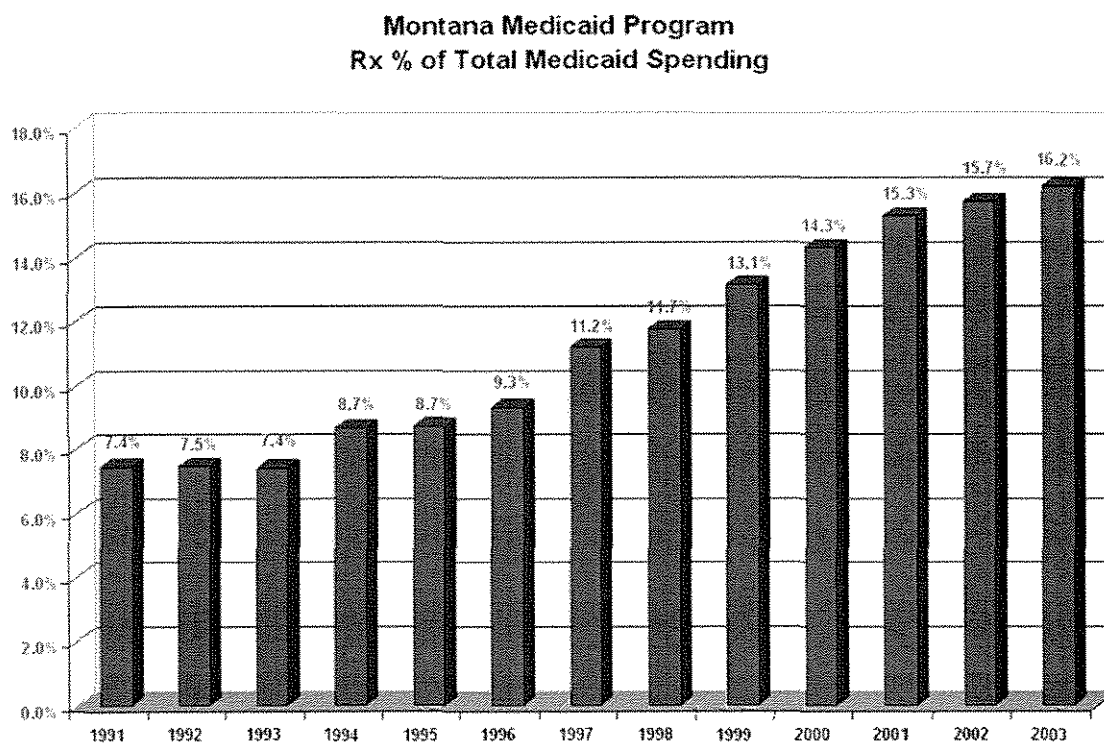


Figure 4

29. For the period 1991 through 2003, AstraZeneca products represented 4.5% of the total reimbursement by the State of Montana for pharmaceutical products (see Figure 5). Likewise, AstraZeneca paid 4.7% of the total rebates paid to the State.

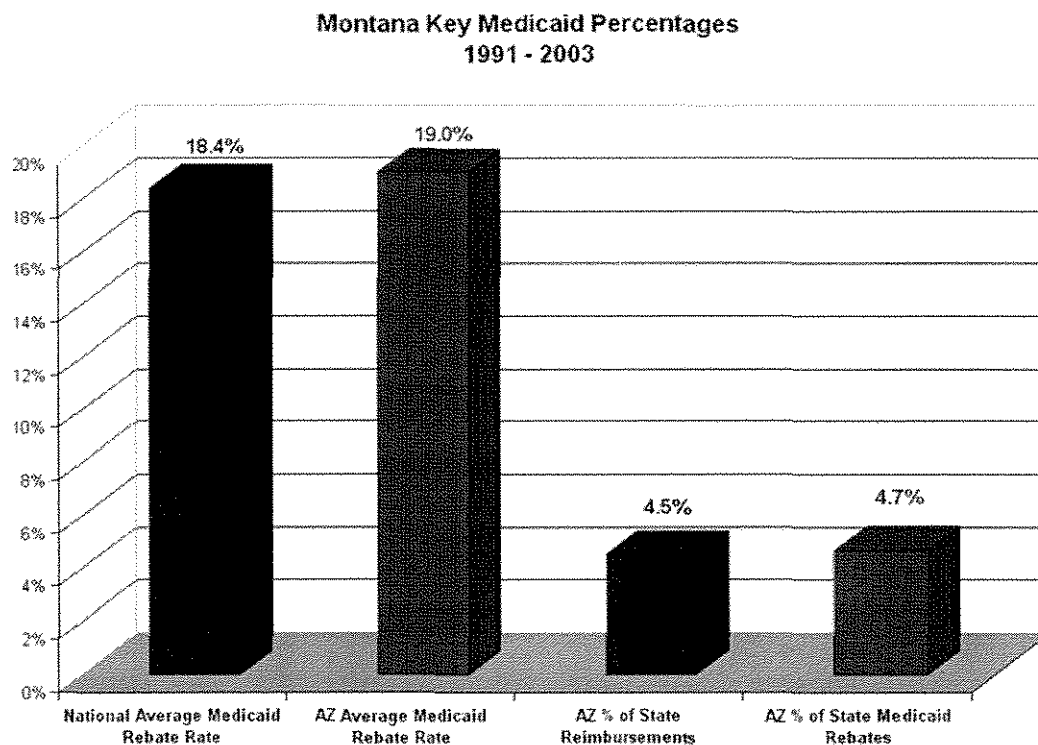


Figure 5

B. ANALYSIS OF ASTRAZENECA'S TOP 5 MEDICAID PRODUCTS

30. Figure 6 shows five AstraZeneca Medicaid products reimbursed by the State of Montana between 1991 and 2004. These five products represent a statistically significant sampling of all AstraZeneca Medicaid products (82.4% of the total expenditures). Within each of these product groupings, there may be multiple nine digit product families (strengths) represented. For example, Prilosec has three product strengths; 10mg: product code 0606, 20mg: product code 0742 and 40mg: product code 0743. For the purpose of this analysis, a single product code was

selected for each group. For Prilosec, the 20mg strength was selected. Prilosec 20mg represents 93.4% of State total ingredient costs for Prilosec between 1991 and 2004.

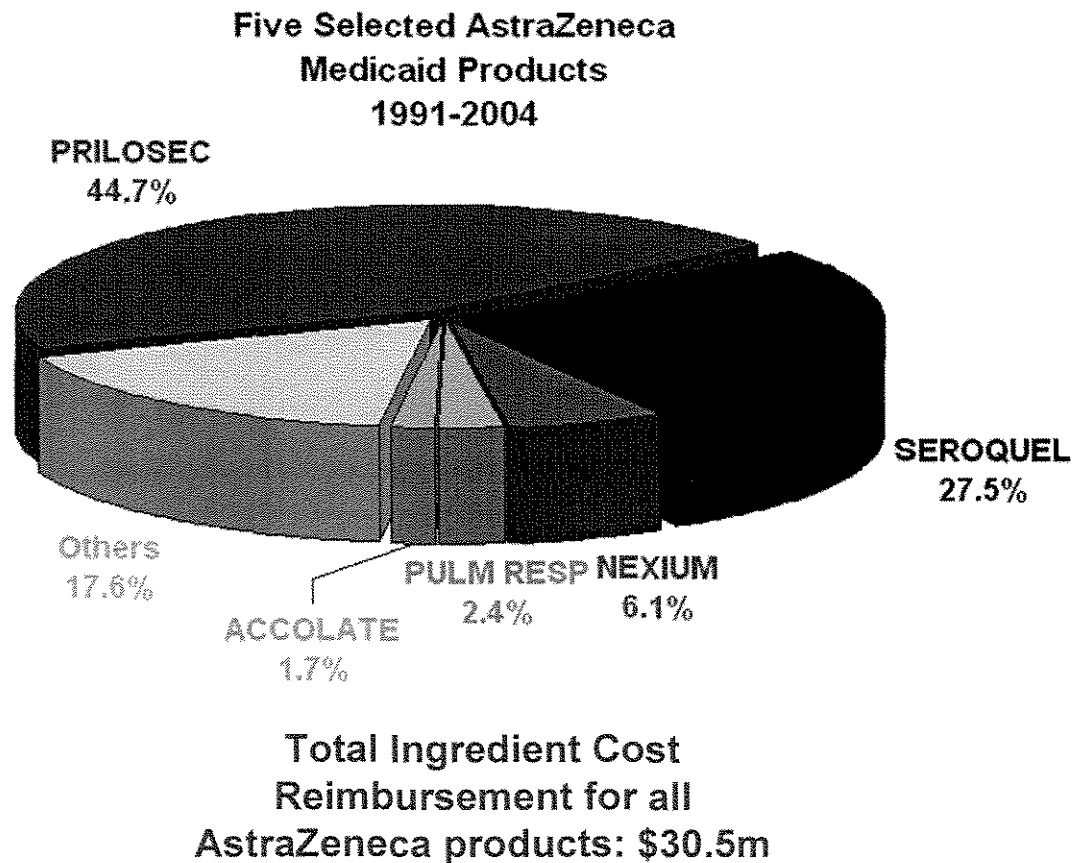


Figure 6

31. Figure 7 shows the pricing trends for Prilosec 20mg from the first reimbursement by the State for the product through Q4 2004. This chart shows the consistency of pricing data for Prilosec through the introduction of generic competition (4Q 2002) and the stability of the State's net cost for the entire time period analyzed. The consistency of the net cost is a key factor in determining if the AWP to WAC spread resulted in increased costs for the State Medicaid agency. On the later portion of the Prilosec chart (4Q 2002 forward) the AMP and BP of Prilosec were lowered as a

result of incentives paid to AMP related customers (non-pharmacy customers) for non-Medicaid related sales that reduced the reported AMP and BP values. These discounts were short-lived, and the eventual AMP and BP values resulted in the net cost of Prilosec to the State actually being reduced.

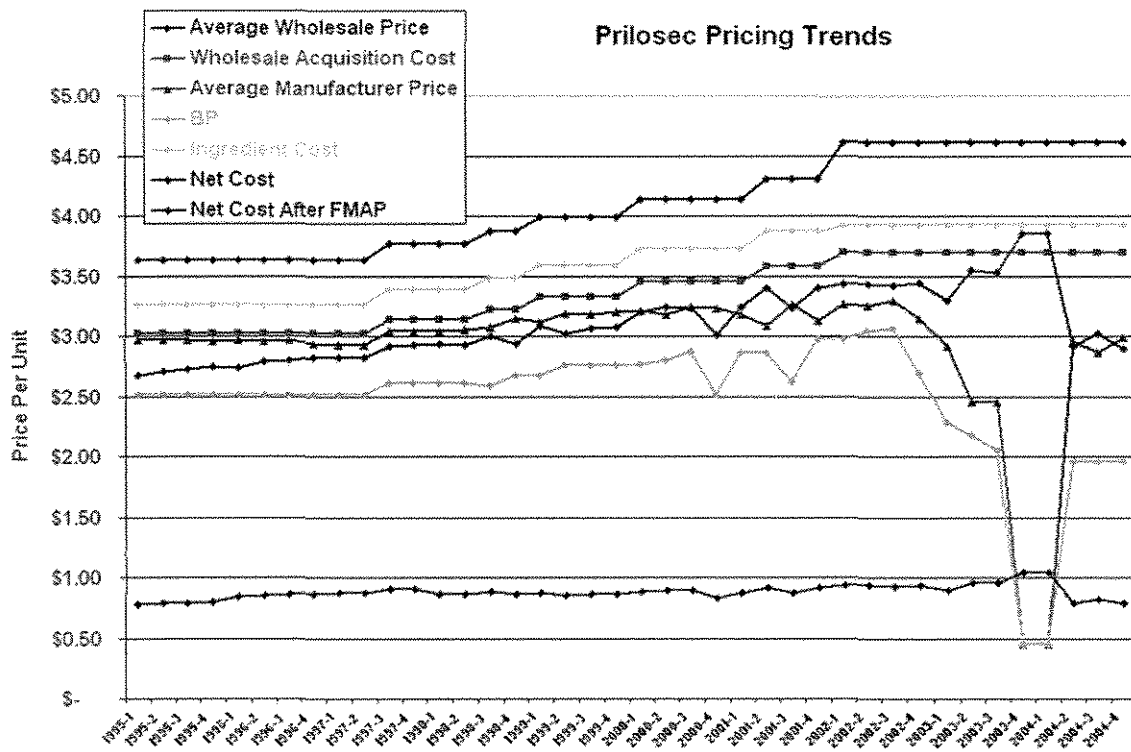


Figure 7

32. Figure 8 shows the relationship of the key Medicaid pricing parameters for Prilosec from the first reimbursement by the State through 4Q 2004. The chart shows a WAC price increase of 22.0% and an AWP increase of 27.1% (the difference a result of the First Data Bank AWP standardization of AWP to 125% of WAC).¹⁶ The AMP for Prilosec ended essentially where it started (0.7% increase) and the BP declined 22.1%. These changes in the AMP and BP resulted in a 72.4% increase in the

¹⁶ AstraZeneca's AWP's for covered outpatient drugs were either 120% or 125% of their respective WACs for all time periods in this case.

Medicaid per unit rebate paid by AstraZeneca to the State Medicaid agency. During this time frame, the cost to State's Medicaid program increased 20.1% before rebates and federal matching funds. After applying rebates, the State's cost increased 8.3% and after federal matching funds, the net per unit cost for AstraZeneca's Prilosec 20mg product increased a scant 0.8%, compared to a 26.9% increase in the CPI-U during the same time frame. The State's net cost during 4Q 2004 was 26.3% of the AMP.

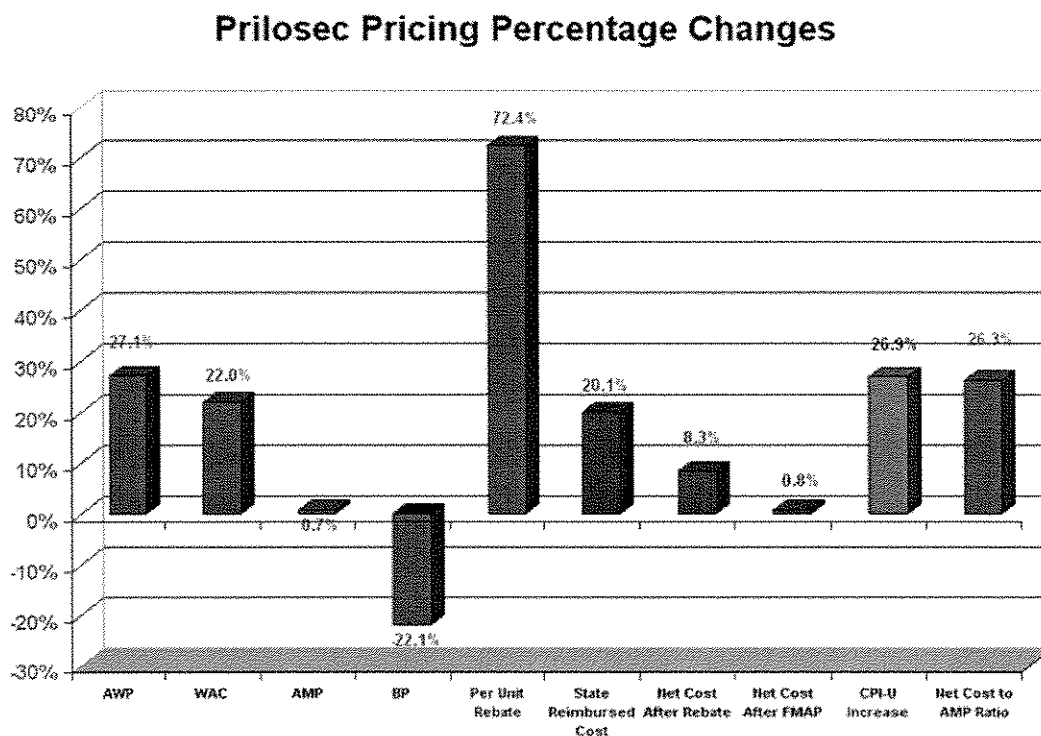


Figure 8

33. Figure 9 shows the pricing trends for Seroquel 200mg from the first reimbursement by the State for the product through Q4 2004. This chart shows the consistency of pricing data for Seroquel throughout the time period analyzed. For Seroquel 200mg, AstraZeneca maintained a consistent AWP to WAC ratio.

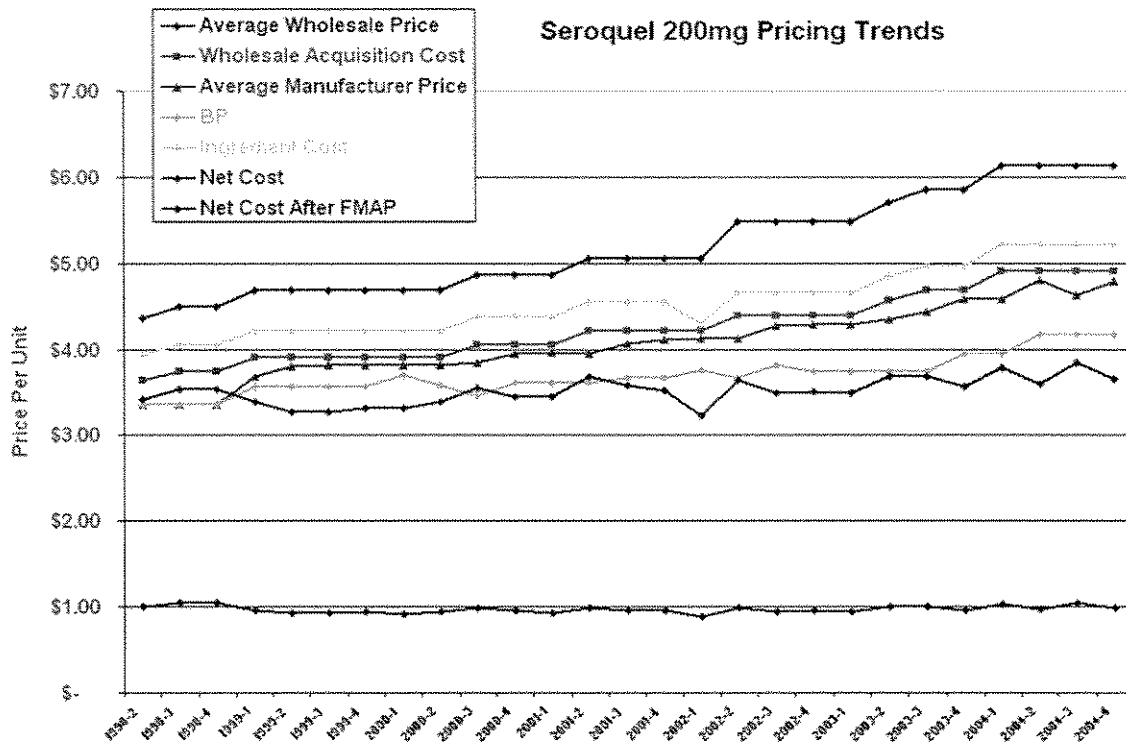


Figure 9

34. Figure 10 shows the relationship of the key Medicaid pricing parameters for Seroquel from the first reimbursement by the State through 4Q 2004. The chart shows a WAC price increase of 34.9% and an AWP increase of 40.5% (the difference a result of the First Data Bank AWP standardization of AWP to 125% of WAC). The AMP for Seroquel 200mg increased 42.5% and the BP increased 24.1%. These changes in the AMP and BP resulted in a 206.3% increase in the Medicaid per unit rebate paid by AstraZeneca to the State Medicaid agency. During this time frame, the cost to State's Medicaid program increased 32.7% before rebates and federal matching funds. After applying rebates, the State's cost increased 6.9% and after federal matching funds, the net per unit cost for AstraZeneca's Seroquel 200mg product actually *decreased* 1.4% compared to a 17.1% increase in the CPI-U during the same time frame. The State's net cost during 4Q 2004 was 20.7% of the AMP.

Seroquel 200mg Pricing Percentage Changes

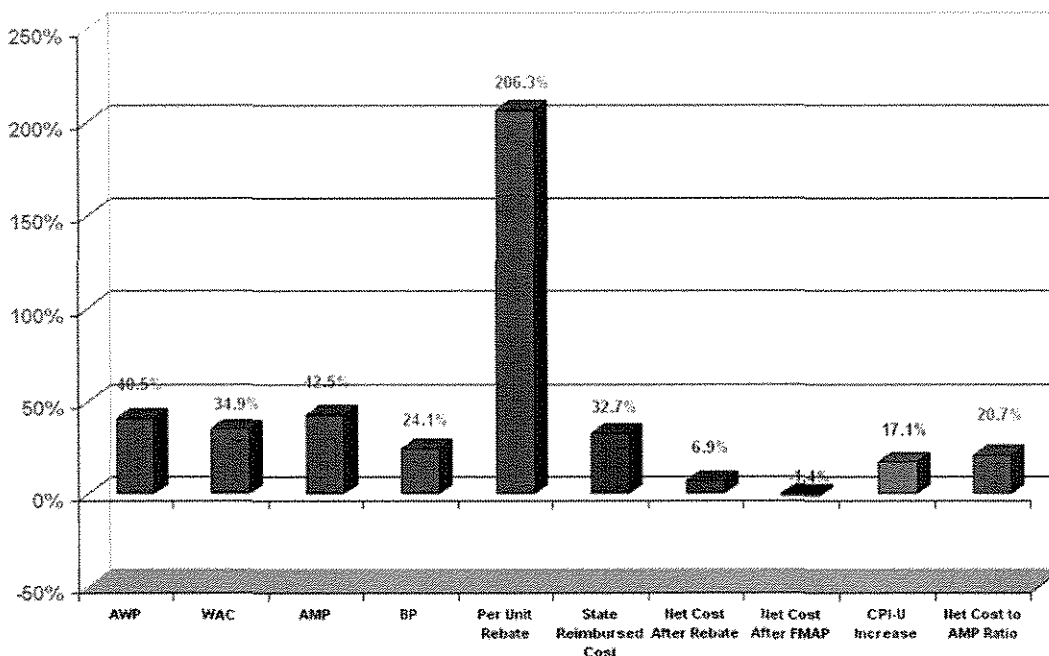


Figure 10

The State Medicaid agency's cost for Seroquel actually decreased slightly over the seven year period from launch through the end of 2004

35. Figure 11 shows the pricing trends for Nexium 40mg from the first reimbursement by the State for the product through Q4 2004. This chart shows the consistency of pricing data for Nexium throughout the time period analyzed. For Nexium 40mg, AstraZeneca maintained a consistent AWP to WAC ratio.

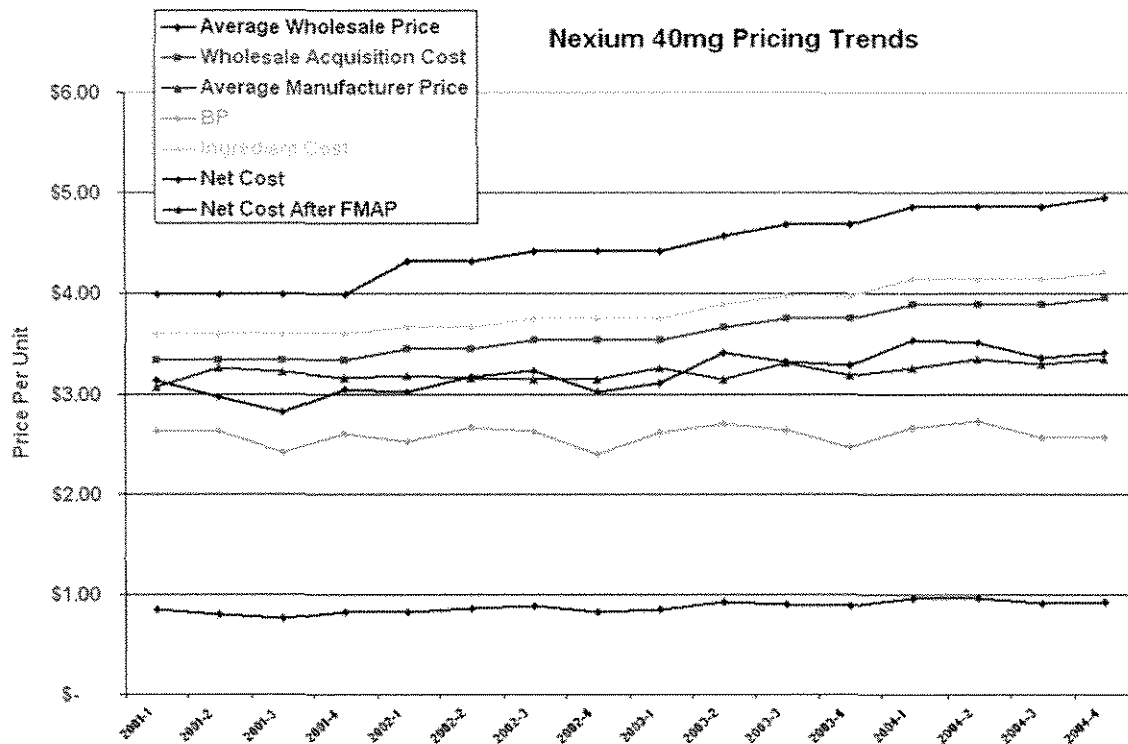


Figure 11

36. Figure 12 shows the relationship of the key Medicaid pricing parameters for Nexium 40mg from the first reimbursement by the State through 4Q 2004. The chart shows a WAC price increase of 18.8% and an AWP increase of 23.8% (the difference a result of the First Data Bank AWP standardization of AWP to 125% of WAC). The AMP for Nexium 40mg increased 9.1% and the BP *decreased* 2.7%. These changes in the AMP and BP resulted in a 70.1% increase in the Medicaid per unit rebate paid by AstraZeneca to the State Medicaid agency. During this time frame, the cost to State's Medicaid program increased 16.9% before rebates and federal matching funds. After applying rebates, the State's cost increased 9.0% and after federal matching funds, the net per unit cost for AstraZeneca's Nexium 40mg product increased 9.8% compared to a 9.1% increase in the CPI-U during the same time frame. The State's net cost during 4Q 2004 was 27.7% of the AMP.

Nexium 40mg Pricing Percentage Changes

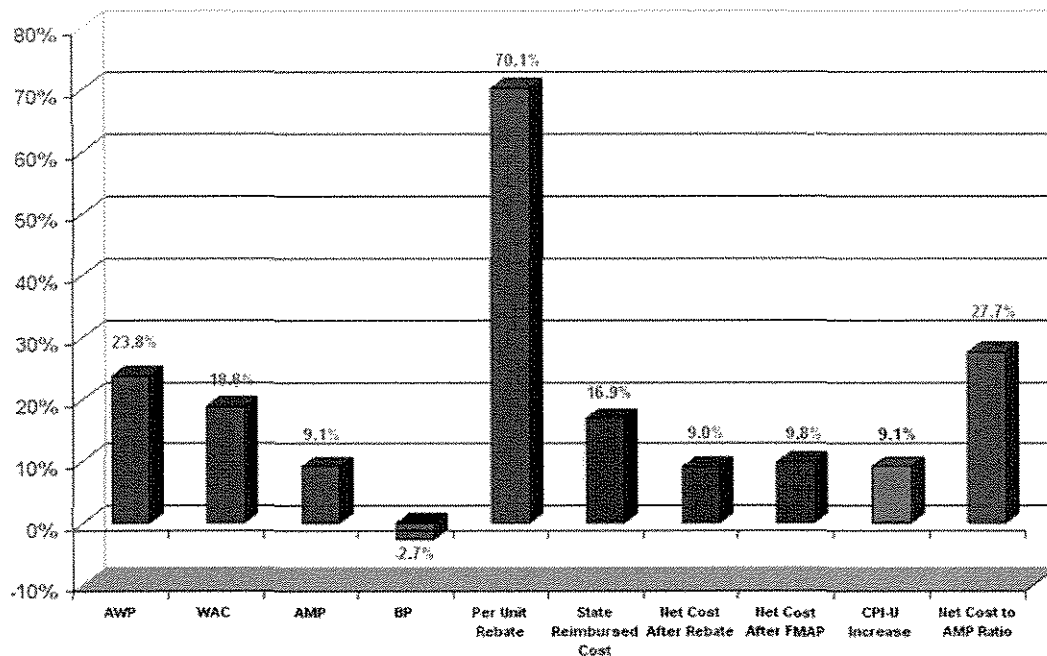


Figure 12

37. Figure 13 shows the pricing trends for Pulmicort Respules 60mls from the first reimbursement by the State for the product through Q4 2004. This chart shows the consistency of pricing data for Pulmicort Respules throughout the time period analyzed. For Pulmicort Respules 60mls, AstraZeneca maintained a consistent AWP to WAC ratio.

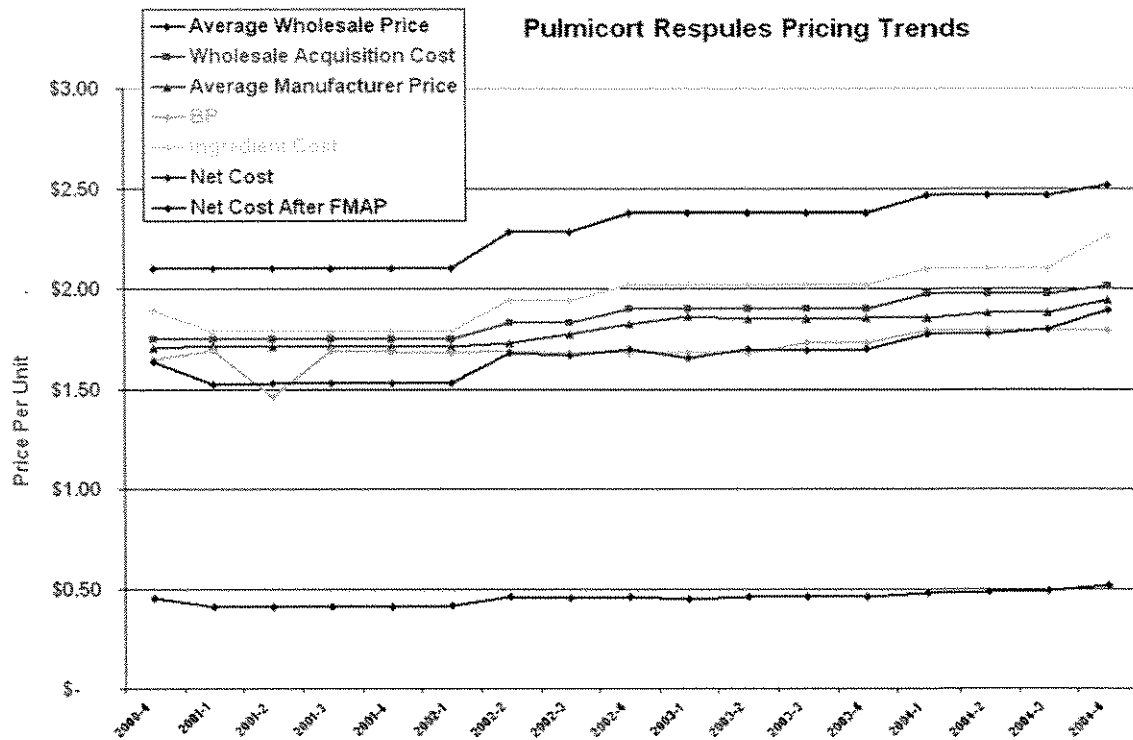


Figure 13

38. Figure 14 shows the relationship of the key Medicaid pricing parameters for Pulmicort Respules from the first reimbursement by the State through 4Q 2004. The chart shows a WAC price increase of 15.1% and an AWP increase of 19.9% (the difference a result of the First Data Bank AWP standardization of AWP to 125% of WAC). The AMP for Pulmicort Respules increased 14.0% and the BP increased 8.9%. These changes in the AMP and BP resulted in a 44.9% increase in the Medicaid per unit rebate paid by AstraZeneca to the State Medicaid agency. During this time frame, the cost to the State's Medicaid program increased 19.9% before rebates and federal matching funds. After applying rebates, the State's cost increased 15.9% and after federal matching funds, the net per unit cost for AstraZeneca's Pulmicort Respules 60mls product increased 13.6% compared to a 9.3% increase in

the CPI-U during the same time frame. The State's net cost during 4Q 2004 was 26.4% of the AMP.

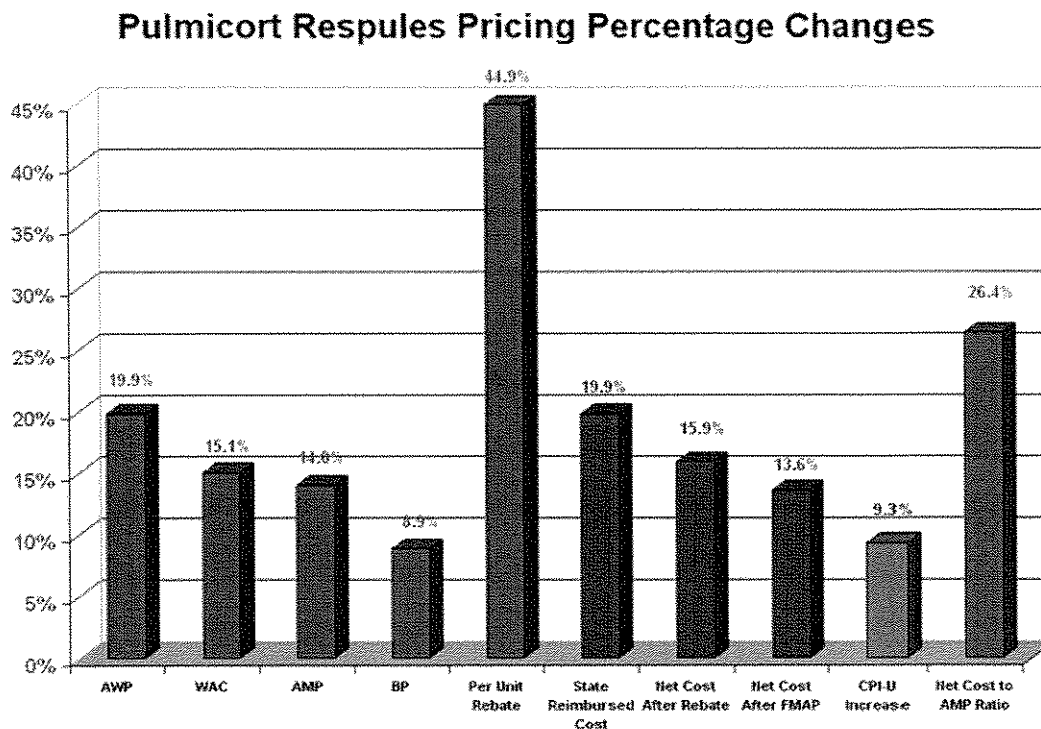
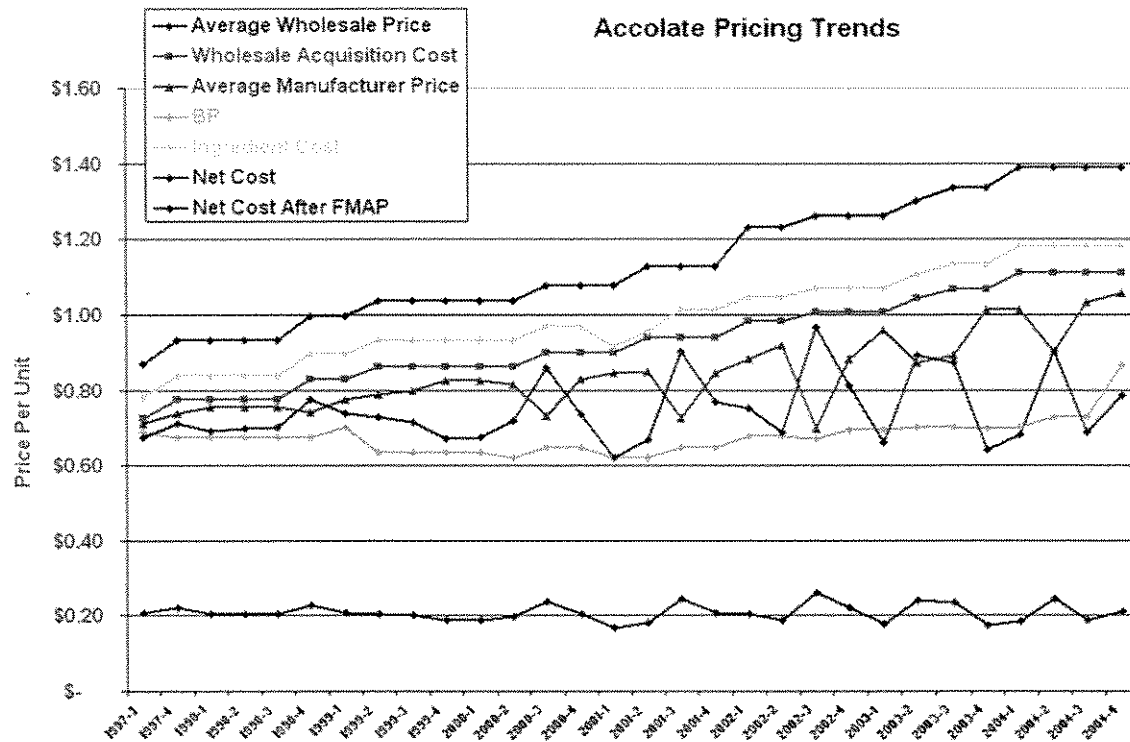


Figure 14

39. Figure 15 shows the pricing trends for Accolate 20mg from the first reimbursement by the State for the product through Q4 2004. This chart shows the consistency of pricing data for Accolate throughout the time period analyzed. For Accolate, AstraZeneca maintained a consistent AWP to WAC ratio.



40. Figure 16 shows the relationship of the key Medicaid pricing parameters for Accolate from the first reimbursement by the State through 4Q 2004. The chart shows a WAC price increase of 53.1% and an AWP increase of 59.5% (the difference a result of the First Data Bank AWP standardization of AWP to 125% of WAC). The AMP for Accolate increased 48.9% and the BP increased 25.9%. These changes in the AMP and BP resulted in a 268.7% increase in the Medicaid per unit rebate paid by AstraZeneca to the State Medicaid agency. During this time frame, the cost to State's Medicaid program increased 50.6% before rebates and federal matching funds. After applying rebates, the State's cost increased 16.0% and after federal matching funds, the net per unit cost for AstraZeneca's Accolate product increased 1.6% compared to an 18.5% increase in the CPI-U during the same time frame. The State's net cost during 4Q 2004 was 20.1% of the AMP.

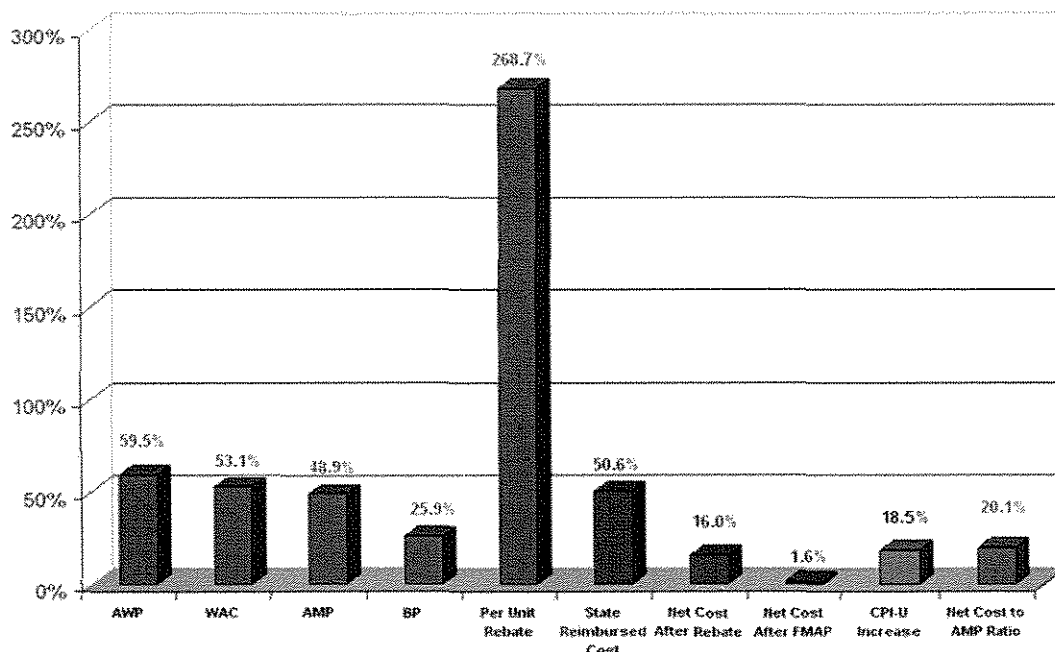


Figure 16

C. ANALYSIS OF DR. HARTMAN'S DECLARATION

41. The estimates of damages and penalties made by Dr. Hartman are fundamentally flawed in that they do not establish, identify or apply a standard for “excessively large” spreads or deviations in AWP and actual pharmacy reimbursement costs.¹⁷ In fact, no spread was used to determine the estimates of damages and penalties in this case.¹⁸ This approach is inconsistent with Dr. Hartman’s previous analysis of AWP spread pricing where he established a “yardstick methodology” based on industry surveys to develop an expected spread to be compared against actual spreads in order to identify and assign damage and penalty estimates.¹⁹ Dr. Harman develops his AWP spread expectation theory in section C of his report, where he chooses to apply a yardstick of any realized spread that exceeds 30% as “excessively large”.²⁰ Had

¹⁷ Declaration of Dr. Raymond S. Hartman: Calculation of Damages to Montana, June 13, 2006 ¶11.

¹⁸ Declaration of Dr. Raymond S. Hartman: Calculation of Damages to Montana, June 13, 2006 ¶14.

¹⁹ Declaration of Raymond S. Hartman: In re Pharmaceutical Industry AWP Litigation, December 15, 2005 ¶¶ 17-22.

²⁰ Declaration of Raymond S. Hartman: In re Pharmaceutical Industry AWP Litigation, December 15, 2005 ¶¶ 59-60.

this approach been utilized in this case, none of AstraZeneca's branded covered outpatient drugs would have met the definition of "excessively large".

42. His estimates of damages and penalties are also flawed due to his failure to include historical changes in acquisition costs for retail pharmacies. During the time frame between 1991 and 2004, wholesaler pricing policies have changed significantly with respect to retail pharmacies. In the early 1990s, wholesalers routinely charged sales markup fees to their retail pharmacy customers. Wholesaler profitability rates reflect these sales markups ranging from 6.82% in 1991 to 5.12% in 1995.²¹ Dr. Hartman ignores these facts and trends in his evaluation of claims without respect to wholesaler sales markups to retail pharmacies for the entire time frame of his analysis. A proper inclusion of these markups would have significantly reduced the number of claims included in the fraudulent category.

²¹ National Wholesaler Druggist Association Fact Report.

D. THE IMPACT OF DISPENSING FEES

43. In addition to setting the Medicaid product reimbursement levels, state Medicaid agencies are also required to establish the level of dispensing fee reimbursement to be paid to retail pharmacies for dispensing Medicaid prescriptions. It is the combination of the product reimbursement basis (e.g., Montana's reimbursement rate of AWP – 10%) and the dispensing fee (e.g., Montana's dispensing fee of \$2.00) that determines the net reimbursement to a retail pharmacy when dispensing a Medicaid prescription. In the case of Montana, the pharmacy dispensing fee reimbursement level has historically been set well below pharmacies' actual dispensing costs. A 2002 survey of Montana retail pharmacies²² showed the average dispensing cost for each Medicaid prescription was \$9.84, compared to the average Medicaid dispensing fee reimbursement of \$4.71. Similarly, a recently published national survey of retail pharmacies²³ showed the average dispensing costs for each Medicaid prescription in Montana was \$11.46, and a 2005 study of pharmacies in 13 states yielded an average dispensing cost of \$9.62.²⁴

44. In evaluating whether the State reimbursed Montana pharmacies in excess of their costs, the actual dispensing cost and reimbursement dispensing fee must be considered. In Dr. Hartman's declaration, he equates the actual dispensing cost and reimbursed dispensing fee,²⁵ when in fact they are quite different. Figure 17 shows the actual retail pharmacy net profit (loss) for the five AstraZeneca products for 2002

²² Montana Pharmacy Association 2002 Survey of Montana Community Pharmacies.

²³ Grant Thornton LLP, National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, January 2007.

²⁴ The Center for Pharmacoeconomic Studies, The University of Texas at Austin, Summer 2005.

²⁵ Declaration of Dr. Raymond S. Hartman: Calculation of Damages to Montana, June 13, 2006 ¶ 15.

(comprising 84.4% of Montana's Medicaid expenditures²⁶). The chart shows that for all of these products, pharmacies incurred a slight to significant loss when the impact of the dispensing fee (using the Montana Retail Pharmacy survey figures) is considered. The chart also shows the impact of utilizing Dr. Hartman's "but for" reimbursement scheme (actual acquisition cost + dispensing fee) which, while saving money for the State Medicaid agency, significantly increases losses to retail pharmacies. Using Dr. Hartman's "but for" pharmacy reimbursement approach would create an unsupportable loss position for Montana retail pharmacies dispensing Medicaid prescriptions. Alleging that AstraZeneca manipulated its prices in order to enrich pharmacies for dispensing Medicaid prescriptions shows a fundamental lack of understanding of the profitability dynamics at the retail pharmacy level for branded outpatient drugs covered under the Montana Medicaid program.

²⁶ One NDC per product used in this analysis.

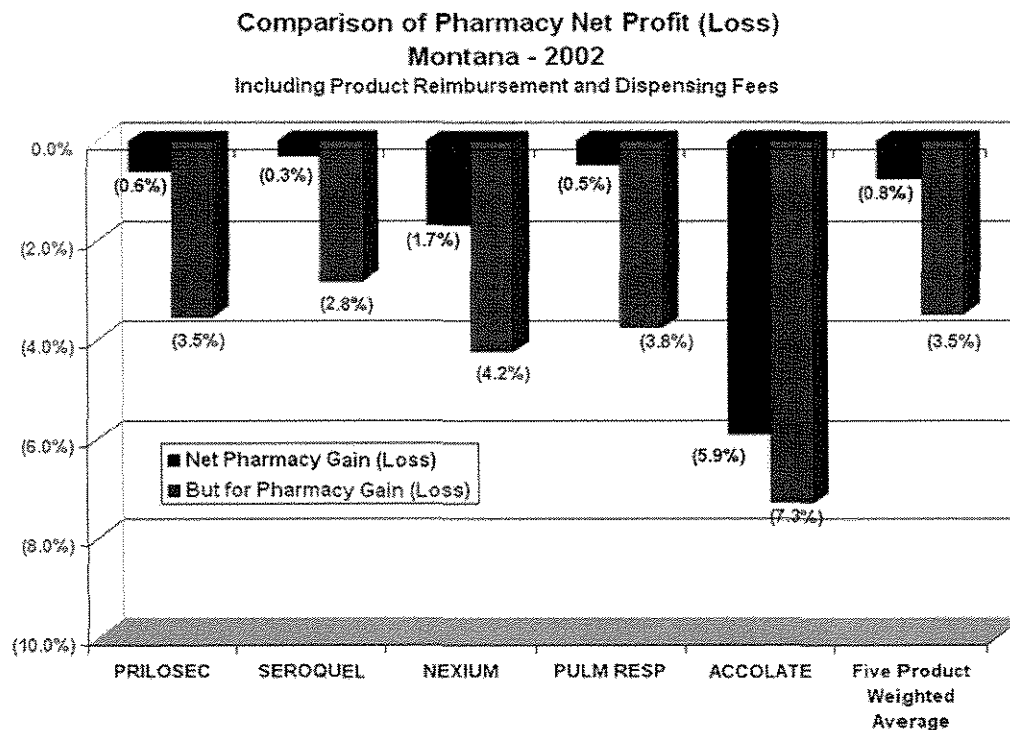


Figure 17

45. Using AstraZeneca's Prilosec 20mg bottle of 30 (NDC 00186-0742-31) as an example, retail pharmacies in the State of Montana were reimbursed \$1,595,597.32 for 11,416 prescriptions (405,139 Medicaid units) during 2002.²⁷ The WAC for the product was \$3.691667 per Medicaid unit. Using Dr. Hartman's assumption of pharmacy acquisition cost equal to WAC, the "but for" reimbursement amount for Montana's retail pharmacies would be \$1,549,407.65 (405,139 Medicaid units * WAC of \$3.691667 plus 11,416 prescriptions * Montana's dispensing fee of \$4.71). While this approach would certainly have reduced Medicaid expenditures (by \$46,189.67 or 2.9%) the pharmacies would have incurred a loss of \$58,564.07 (based on 405,139 Medicaid units * WAC of \$3.691667 plus 11,416 prescriptions * Montana pharmacists' actual dispensing costs of \$9.84). As it is, assuming the pharmacies purchased products at WAC (i.e., no wholesaler markups) they realized a

²⁷ Medicaid Claim Utilization from the Centers for Medicare & Medicaid Services

net loss of \$12,374.40 (-0.8%) on AstraZeneca's Prilosec product in 2002.²⁸ Clearly, this level of reimbursement could in no way be considered "excessively large" nor does it indicate any price manipulation on the part of AstraZeneca to enrich retail pharmacies within the Medicaid program.²⁹

²⁸ Actual Montana reimbursement of \$1,595,597.32 less estimated pharmacy cost of \$1,607,971.12 = (\$12,374.40) loss (-0.8%)

²⁹ On July 1, 2002, Montana changed its reimbursement rate for pharmaceutical drugs from AWP-10% to AWP-15%. Declaration of Dr. Raymond S. Hartman: Calculation of Damages to Montana, June 13, 2006 ¶ 25 n. 33. Consequently, for years after 2003, the net loss Montana pharmacies experienced for dispensing AstraZeneca's covered outpatient drugs would be greater.